

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effects of pre-bronchoscopy administration of intravenous hydrocortisone in patients with chronic obstructive pulmonary disease: A randomized, double blind, placebo controlled trial

Protocol summary

Summary

(1) Objectives; Effects of pre-bronchoscopy administration of intravenous hydrocortisone in patients with chronic obstructive pulmonary disease (2) Design: A double blind, single center, clinical trial design will conduct in 90 patients with COPD. Random assignment of subjects in both intervention and control groups will categorize (blocking). (3) Setting and conduct; 90 patients with COPD that need bronchoscopy, will divide randomly to two groups (intervention and control groups) and after signing permission form, underwent bronchoscopy (5) Intervention; Neither physicians, nurses or patients know which patient is located either in intervention or control group. In each of the intervention and control groups, the Fiberoptic Bronchoscopy (FB) will perform and the measurement of PFT, Hemoglobin oxygen saturation, cough score and vital signs will record on a validated self-made checklist before and after procedure. In intervention group intravenous hydrocortisone 200 mg in 5 ml, and for the subjects of the control group, the same volume of saline, will administer 2 hours before FB. Finally results will compare between two groups. (6) main outcome measures; primary outcome variables included, PFT, vital signs, Hemoglobin oxygen saturation and cough severity. we do not have secondary variable outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110922566N1**

Registration date: **2015-12-30, 1394/10/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-30, 1394/10/09

Registrant information

Name

Seyed Mehdi Hashemi Bajgani

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 3211 8078

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Kerman University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of pre-bronchoscopy administration of intravenous hydrocortisone in patients with chronic obstructive pulmonary disease: A randomized, double blind, placebo controlled trial

Public title

Effects of pre-bronchoscopy administration of

intravenous hydrocortisone in patients with chronic obstructive pulmonary disease

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria; " diagnosed with chronic obstructive pulmonary disease and FEV1/FVC ratio less than 70%" " history of smoking" "the need of bronchoscopy for the diagnostic studies like hemoptysis, tuberculosis or lung mass". exclusion criteria; "diagnosis of asthma,cystic fibrosis" " oral or intravenous corticosteroid therapy or inhaled corticosteroid dose of 600 micrograms or more per day" " therapeutic bronchoscopy" " intubation".

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Jomhuri Islami Blv, Central Organization

City

kerman

Postal code

Approval date

2013-09-23, 1392/07/01

Ethics committee reference number

52/92/5

Health conditions studied

1

Description of health condition studied

chronic obstructive pulmonary disease

ICD-10 code

J40, J41,

ICD-10 code description

chronic lower respiratory diseases

Primary outcomes

1

Description

vital sign

Timepoint

pre-bronchoscopy and 1 hour after bronchoscopy

Method of measurement

termometer,choronometer,sphygmanometer

2

Description

cough

Timepoint

pre-bronchoscopy and 1 hour after bronchoscopy

Method of measurement

numbering score from 1 to 10

3

Description

spirometry

Timepoint

pre-bronchoscopy and 1 hour after bronchoscopy

Method of measurement

spirometer

4

Description

saturation of blood oxygen

Timepoint

pre-bronchoscopy and 1 hour after bronchoscopy

Method of measurement

pulseoxymeter

Secondary outcomes

empty

Intervention groups

1

Description

200 mg hydrocortisone diluted in 10 cc iv 2 hour before bronchoscopy

Category

Treatment - Drugs

2

Description

10 cc normal salin iv 2 hour before bronchoscopy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Dr. Seyedmehdi Hashemi

Street address

Imam Highway ,Afzalipour Hospital

City

kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Kerman University of
Medical Sciences

Full name of responsible person

DR.Abbas Pardakhti

Street address

Jahad Blv.Vice chancellor for research,Kerman
University of Medical Sciences

City

kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research,Kerman University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

kerman University of Medical Science

Full name of responsible person

Dr. Seyedmehdi Hashemibajgani

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty